

Thoracic Cancer Patients Involvement in Clinical Trials

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Editorial

The direct consequences of the insufficient patient participation in thoracic cancer clinical trials and particularly in lung cancer research may be the overall slow rhythm of scientific advance. The emergence of new concepts, validation of new approaches such as combined treatment modalities or adjuvant chemotherapy, new cytotoxic drugs, new targeted-agents clearly offer the patient new possibilities of longer survival. However, these results are only observed in the setting of clinical trials and encounter difficulties of translation to the global lung cancer patient population. Notwithstanding, recent major advances in thoracic cancer treatment have been achieved. The improvement of the condition of the general population is slow and, in our opinion, the low participation of lung cancer patients in clinical trials is not only a quantitative concern, but also, a qualitative one. Several studies of sociodemographic features characterizing cancer patient accrual in clinical trials have highlighted that some important subsets of patients are underrepresented in research programs, particularly. The direct consequences of the insufficient patient participation in thoracic cancer clinical trials and particularly in lung cancer research may be the overall slow rhythm of scientific advance. The emergence of new concepts, validation of new approaches such as combined treatment modalities or adjuvant chemotherapy, new cytotoxic drugs, new targeted-agents clearly offer the patient new possibilities of longer survival.

However, these results are only observed in the setting of clinical trials and encounter difficulties of translation to the global lung cancer patient population. Notwithstanding, recent major advances in thoracic cancer treatment have been achieved. The improvement of the condition of the general population is slow and, in our opinion, the low participation of lung cancer patients in clinical trials is not only a quantitative concern, but also, a qualitative one. Several studies of sociodemographic features characterizing cancer patient accrual in clinical trials have highlighted that some important subsets of patients are underrepresented in research programs, particularly, patients older than 75 years, persons with poor socio-economic conditions, people living without insurance, and ethnic minorities. The case of the former group of patients, i.e., patients older than 75 years, has been extensively discussed. Most of the therapeutic controlled trials performed during the past 15 years have systematically excluded patients older than 70 to 75 years. Therefore, extrapolations of therapeutic advances observed in younger patients with good clinical status are speculative. Development of specific research in the elderly is urged.

Consequently, impact of new strategies in the general population cannot spread far from the original population of young patients treated in clinical trials. Similarly, patients afflicted by common comorbidities such as coronary artery, renal insufficiencies, or severe chronic obstructive pulmonary disease (COPD), are frequently excluded from clinical trials. However, when considering the Charlson comorbidity Index (CCI) in a general (unselected) population of lung cancer, one can easily observed that most of the patients are afflicted by a CCI

or more. The under representation of ethnic minorities is also an important concern, because, in several countries such as in United States of America and in New-Zealand, these patients are afflicted by a poorer prognosis when compared with non-Hispanic Caucasian sub populations. One can hypothesize that the improvement of survival, such as it is regularly observed in clinical trials, cannot be directly transposed because the population accrued in these studies did not reflect the heterogeneity of the lung cancer population sociodemographic characteristics. In our opinion, there are two different ways to reach this goal. The first would be to improve the accessibility of clinical trials for the patients, i.e., improve the information delivered to patients regarding research options for their disease; the second would be to change our method of designing clinical trials to more widely accrue the reality of lung cancer patient demography in the current research programs. Improving the accessibility of clinical trials has been attempted in several ways.

Educational booklets about the clinical trial have been proposed. The aforementioned letter is a very interesting attempt to present the patient, before their first medical appointment, what is a clinical research option and why this option may be the best therapeutic option. In their publication, the authors suggested that the participation in clinical trials in thoracic oncology programs have trended toward improvement after this letter was introduced into their routine practice, patients older than 75 years, persons with poor socio-economic conditions, people living without insurance and ethnic minorities. The case of the former group of patients, i.e., patients older than 75 years, has been extensively discussed.⁹ Most of the therapeutic controlled trials performed during the past 15 years have systematically excluded patients older than 70 to 75 years. Therefore, extrapolations of therapeutic advances observed in younger patients with good clinical status are speculative. Development of specific research in the elderly is urged.¹⁰ consequently, impact of new strategies in the general population cannot spread far from the original population of young patients treated in clinical trials [1-5].

Similarly, patients afflicted by common comorbidities such as coronary artery, renal insufficiencies, or severe chronic obstructive pulmonary disease (COPD), are frequently excluded from clinical trials. However, when considering the Charlson comorbidity Index (CCI) in a general (unselected) population of lung cancer, one can easily observed that most of the patients are afflicted by a CCI 3 or more. The under representation of ethnic minorities is also an important concern, because, in several countries such as in United States of America and in New-Zealand, these patients are afflicted by a poorer prognosis when compared with non-Hispanic Caucasian sub populations. One can hypothesize that the improvement of survival, such as it is regularly observed in clinical trials, cannot be directly transposed because the population accrued in these studies did not reflect the heterogeneity of the lung cancer population sociodemographic characteristics. In our opinion, there are two different ways to reach this goal. The first would be to improve the accessibility of clinical trials for the patients, i.e., improve the information delivered to patients regarding research options for their disease; the second would be to change our method of designing clinical trials to more widely accrue the reality of lung cancer patient demography in the current research programs. Improving the accessibility of clinical trials has been attempted in several ways. Educational booklets about the clinical trial have been proposed. The aforementioned letter is a very interesting attempt to present the patient, before their first medical appointment, what is a clinical research option and why this option may be the best therapeutic option. In their publication, the authors suggested that the participation in clinical trials in thoracic oncology programs have trended toward improvement after this letter was introduced into their routine practice.

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